DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 27, 2015

Permobil AB
Jan Åström
Director Quality & Environment
Per Uddens VAG 20, Timra,
SE 86123 Vasternorrland
SWEDEN

Re: K143180
Trade/Device Name: F3 Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 10, 2015
Received: February 10, 2015

Dear Mr. Åström:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143180

Device Name
F3 Powered Wheelchair

Indications for Use *(Describe)*
The intended use of the F3 powered wheelchair is to provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Permobil AB
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Contact Person: Jan Åström
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Date Prepared: February, 2015

Trade name: F3

Common or Usual Name:
Powered Wheelchair

Classification Name:
Powered wheelchair (890.3860)

Product Code:
ITI

Predicate Devices:
M300 & M400 (K103477) manufactured by Permobil AB.

Intended use:
The intended use of the F3 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Description of device:
F3 Powered Wheelchair is battery powered, front wheel motor driven and is controlled by the R-net 120 amp controller. The user interface is a joystick.

The F3 is powered by two 12VDC 60Ah or tow 12VDC 73Ah, Group M34 batteries or Group M24, approximate driving range on fully charged batteries is up to 25km (15.5 miles), depending on use and the terrain the chair is driven on. The chair frame is a steel construction and includes two front drive wheels with drive units (motor, gear and brake), two batteries and two rear pivoting casters. Depending on the user's needs, the joystick motor control is mounted to the left or right armrest.

When the user activates the joystick, the controller receives a signal to release the brakes.
With the brakes released, the chair is allowed to move in the direction the joystick is actuated.
When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user to stop by letting go of the joystick.

Comparison to Predicate Devices:
The F3 is substantially equivalent to the **M300 & M400** (#K103477). The F3 has the same intended uses and similar indications, technological characteristics and principles of operation. F3 has slightly more power than compared predicated device but no changes in speed occur. F3 has the same option in tilt, recline and elevation functions as the predicated device, see below table. These functions working in the same technological characteristics as the predicated M300 & M400.

Functions	M300 & M400 Predicated device	F3 Submitted device
Tilt	X	X
Recline	X	X
Elevation	X	X

The submitted device differs from the predicated device on its position of the drive wheel. The predicated device have a shorter turning radius and are less comfortable compared to a front driven chair because the placement of the tires on the chassis. A front wheel driven chair have a better obstacle climbing than a central driven chair. The submitted device are tested and having same or improved results as the already predicated device. These technological differences do not raise any new issues in safety and effectiveness.

Other specific differences between the F3 and the M300 & M400 (K103477) are:
* F3 has slightly larger pivoting caster wheels than the predicated device.
* Slightly specific dimensions such as height, length, weight and turning radius are different.

These minor technological differences between the **F3** and its predicate device **M300 & M400** raise no new issues of safety or effectiveness. Performance data demonstrates that the F3 is as safe and effective as the **M300 & M400**. Thus, the F3 is substantially equivalent.

Non-Clinical Testing:
The F3 complies to the below standards:

Standard	**Name**	**FDA recognized standards**
ISO 7176-1	Determination of static stability	16-158
ISO 7176-2	Determination of dynamic stability of electric wheelchairs	16-159
ISO 7176-3	Determination of efficiency of brakes	16-192
ISO 7176-4	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	16-162
ISO 7176-5	Determination of dimensions, mass and maneuverings space	16-163
ISO 7176-6	Determination of maximum speed, acceleration and deceleration of electric wheelchairs	16-29
ISO 7176-8	Requirements and test methods for static, impact and fatigue strengths	-
ISO 7176-9	Climatic tests for electric wheelchairs	16-167
ISO 7176-10	Determination of obstacle-climbing ability of electrically powered wheelchairs	16-164
ISO 7176-11	Test Dummies	16-190
ISO 7176-14	Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	16-165
ISO 7176-15	Requirements for information disclosure, documentation and labelling	16-27
ISO 7176-16	Resistance to ignition of postural support devices	16-191
ISO 7176-19	Wheeled mobility devices for use in motor	-
ISO 7176-21	Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters	16-166

Clinical Testing:
Clinical testing is not applicable.

Conclusions:
The **F3** and the predicated device **M300 & M400** are substantial equivalence. F3 has the same general intended use and similar indications, principles of operation, and similar technological characteristics as the previously cleared **M300 & M400**. The differences between the devices are minor and do not raise any new issues of safety and effectiveness because both devices have passed all necessary testing and are considered safe and effectives for use.